Promoting Compliance

**Basic Approach**

Earning the trust of society is critical for Terumo to continue to fulfill its Group mission of “Contributing to Society through Healthcare.” Terumo, together with all of its associates, strives to protect its reputation, which is an invaluable asset, and to further build trust with society. To achieve this, every Terumo associate must make the right decisions and do the right things. The Terumo Group Code of Conduct is a guide to help Terumo associates make the right decisions in their everyday actions.

Terumo makes every effort to ensure that all associates around the world not only directors and officers, engage in fair business practices, abide by laws and regulations, and follow the highest ethical standards when serving all stakeholders, including the patients and healthcare professionals that use our products, and when practicing social responsibility, always keeping this Code of Conduct in mind. For this purpose, Terumo has established an environment that enables associates to better understand the importance of the Code of Conduct through means such as constantly providing training tailored to each workplace.

**Compliance System**

At Terumo, the Internal Control Committee, which is responsible for enacting the Internal Control System of the Terumo Group in accordance with the Internal Control System Design Basic Policy approved by the Board of Directors, shall deliberate and make decisions regarding important policies related to compliance, and regularly report the status of these activities to the Board of Directors and Audit and Supervisory Committee.

Under the leadership of the Chief Legal Officer (CLO) and centered on the Legal and Compliance Department, we create compliance-related rules, perform training and education, and conduct monitoring to quickly discover and ascertain compliance issues through coordination with the compliance officers who are in charge of promoting compliance-related activities at each Group company.

In the event that a significant compliance violation occur, a response team shall be immediately organized under the direction of the Chairman of the Internal Control Committee, and that team shall, in addition to handling and resolving the matter, report and make proposals to the Internal Control Committee regarding the cause and recurrence prevention measures.

**Compliance Education**

Terumo conducts compliance education with the aim of improving compliance awareness among all associates and ensuring understanding of and compliance with relevant laws and regulations.

### Major Compliance Training Programs (Terumo Corporation)

<table>
<thead>
<tr>
<th>Name</th>
<th>Scope of Participation</th>
<th>Format</th>
<th>Subjects</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terumo Group Code of Conduct</td>
<td>All directors, officers, and associates</td>
<td>E-learning program</td>
<td>Training on the Terumo Group Code of Conduct</td>
<td>Once a year</td>
</tr>
<tr>
<td>Antitrust and anti-corruption</td>
<td>Directors, officers, and some associates</td>
<td>E-learning program</td>
<td>Fair transactions and prevention of corruption in business activities</td>
<td>Once a year</td>
</tr>
<tr>
<td>Interactions with healthcare professionals</td>
<td>Associates in sales branches and Companies</td>
<td>Branch training, e-learning program</td>
<td>Maintenance of appropriate relations with healthcare professionals</td>
<td>At least once a month</td>
</tr>
<tr>
<td>Level-based training</td>
<td>Associates at specific levels</td>
<td>Group training</td>
<td>Compliance education as part of training for early-career associates and associates being promoted to mid-level and management positions</td>
<td>Once a year</td>
</tr>
<tr>
<td>Officer training</td>
<td>Officers</td>
<td>Group training</td>
<td>Compliance education</td>
<td>Once every two-three months</td>
</tr>
</tbody>
</table>
Promoting Compliance

Compliance Initiatives

Whistle-Blowing System

When we encounter any compliance issues, it is important to promptly take the appropriate measures, such as investigation, preventive action, disciplinary action, and/or recurrence prevention. For this reason, we have established the Group Compliance Violations Reporting and Anti-Retaliation Policy, which urges associates to promptly report any compliance-related issues internally while ensuring that they will not suffer any retaliation as a result.

Based on this policy, Terumo operates a whistle-blowing system through which associates can make reports or receive consultation with regard to compliance violations. Through this system, associates can contact internal venues, legal advisors, or external reporting venues operated by independent third-party organizations via email, mail, telephone, or other means. In addition, a whistle-blowing system relating to the Board of Directors was established in July 2017, enabling associates to contact the Audit and Supervisory Committee.

Prevention of Harassment

Terumo’s work regulations in Japan explicitly forbid abuses of power and sexual harassment, regardless of gender orientation or gender identification (members of the LGBT community), as well as activities intended to put individual associates at a disadvantage due to reasons such as pregnancy or roles as a parent or caregiver. In addition, we have established a harassment intranet page where associates in Japan will find our Harassment Prevention Guidelines. These measures are indicative of our stance toward harassment. From fiscal 2017, December–January has been designated as a period for promoting harassment prevention awareness in Japan. Initiatives during this period include the transmission of messages, administration of surveys, and conducting of e-learning programs for all associates. Managers, meanwhile, periodically attend training sessions that provide examples of harassment relevant to daily business activities. Through these initiatives, we are constantly working to raise awareness of harassment prevention.

Furthermore, a new intranet page detailing our efforts to ensure rigorous compliance was established in April 2020. On this page, associates will find information on our stance toward earnestly embracing compliance and concrete examples of compliance violations and countermeasures. This information is designed to facilitate increased understanding and risk sensitivity among associates.

Harassment Prevention Guidelines

- Sexual harassment, abuses of power, and other forms of harassment are human rights issues that violate the dignity of associates and create a toxic workplace.
- Terumo continuously conducts compliance training and asks associates for written pledges declaring their understanding of the negative impacts of harassment and the disciplinary measures that may be taken against them for engaging in harassment.
- Terumo does not tolerate any form of harassment.
- Terumo strives to increase each associate’s understanding of harassment as well as their ability to address harassment issues as part of its efforts in creating a healthy organization that is not complicit in or tolerant of harassment and where all employees are respectful of one another.
- Terumo urges associates who have encountered any form of harassment to consult with their supervisor or with a human resources or general affairs representative at their workplace or to use internal consultation venues in cases where it is difficult to consult with someone in the regular line of reporting. Reporters of harassment issues will not suffer any retaliation and their privacy will be respected.
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Opposition to Antisocial Forces
Avoiding relationships with antisocial forces is one of Terumo's corporate responsibilities. We therefore strictly refuse to become involved in any relationship with antisocial forces and do not engage in any transactions with companies, other organizations, or individuals with ties to antisocial forces. Furthermore, we work with law enforcement authorities and other agencies to combat antisocial forces.

Anti-Corruption
The Terumo Group expects full compliance with Japan’s Unfair Competition Prevention Act, the U.S. Foreign Corrupt Practices Act, and other anti-corruption laws in the countries and regions in which the Group operates in order to ensure honest and fair business practices.

All Terumo associates observe the Group Anti-Corruption and Anti-Bribery Policy, which clearly stipulates our commitment to preventing corruption and engaging in fair business practices. In addition, we have established the Group Policy for Third Party Anti-Corruption and Anti-Bribery, based on which we request our business partners to comply with anti-corruption laws.

Prohibition of Collusion and Cartels
To prevent associates from becoming involved in collusion and cartels during the course of business activities, the Terumo Group has established the Group Antitrust Policy and is engaged in a Groupwide effort to maintain fair and free competition.

Appropriate Relationships with Healthcare Professionals
Terumo abides by the Fair Competition Code of the Japan Fair Trade Council of the Medical Devices Industry, the Promotion Code of the Japan Federation of Medical Devices Associations, and other industry regulations to ensure that it follows appropriate practices in promoting medical devices and pharmaceuticals to healthcare professionals. We have also established internal rules for this purpose.

Furthermore, the Group Ethical Interactions with Healthcare Professionals Policy was established based on the principles of the codes of ethics of reputable industry associations in the regions in which the Group operates, to guide us in maintaining appropriate relationships with healthcare professionals.

Advertisements and Other Activities for Providing Product Information and Sales Promotions
Terumo strives to conduct appropriate promotional activities. To facilitate these efforts, the Company has established the Terumo Code of Practice and ensures compliance with Japan’s PMD Act (the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics) as well as other relevant laws and regulations. We also abide by various industry codes, such as those set by the Japan Federation of Medical Devices Associations. The relevant divisions review promotional materials prior to use to confirm their legality and the accuracy of the information they contain. In addition, the Promotional Activities Control Department was established within the corporate headquarters in July 2019 to promote compliance with the Guidelines for Prescription Drug Marketing Information Provision released by the Ministry of Health, Labour and Welfare on September 25, 2018. We also work to ensure the appropriateness of promotional activities overseas with major Group companies playing a central role in advancing these activities in compliance with the applicable laws.

Moreover, the Group Rules for Dealing with Off-Label Use were established for global application in January 2016. These rules prohibit all advertisements and promotions soliciting off-label use of Terumo products. In addition, the Terumo (Japan) Rules for Dealing with Off-Label Use were implemented for Japan and other regional rules have been enacted to ensure compliance with the laws of the countries in which we sell our products and to guarantee appropriate promotions.
Promoting Compliance

**Transparent Relationships between Corporate Activities and Medical Institutions**

The supply of advanced medical devices and pharmaceuticals that meet sophisticated needs requires not only the efforts of individual companies but also cooperation with universities and other research and medical institutions at all stages of the process, ranging from research and development to production and sales. Sometimes this cooperation entails monetary compensation. Terumo seeks to ensure transparency in such activities through adherence to high ethical standards.

In Japan, based on voluntary industry rules, Terumo has formulated its Transparency Guideline for the Relationships between Corporate Activities. We follow the provisions of this guideline by disclosing payments of funds to medical institutions and medical professionals.

**Stance on Tax**

Guided by its Group mission of “Contributing to Society through Healthcare,” the Terumo Group conducts business based on strict legal compliance and corporate ethics and aims to achieve sustainable growth and maximize long-term corporate value and meet the expectations of its worldwide stakeholders. In accordance with its Group mission, the Terumo Group takes the following actions in conducting tax management.

1. Terumo Group complies with international taxation rules and the laws of all countries in which it conducts business activities and maintains tax compliance.

2. Terumo Group constructs and maintains appropriate relationships with the tax authorities where the Terumo Group conducts business activities and does not attempt to obtain unfair benefits from the tax authorities by providing unethical gifts to these authorities.

3. Terumo Group considers the balance of each stakeholder’s interest and ensures that an appropriate tax burden is borne while maximizing its corporate value.

**R&D Ethics**

The development of medical devices and pharmaceuticals requires us to conduct animal experiments as well as clinical research on human beings in order to evaluate the safety and efficacy of these products. In its research activities, Terumo always acts in an appropriate manner based on both an ethical and a scientific perspective. We therefore observe the principles of the Declaration of Helsinki* and comply with Good Clinical Practices (GCP) as well as the pharmaceutical laws of countries in which we operate and other relevant regulations and standards. In addition, we have established the internal Research Ethics Review Committee and Institutional Animal Care and Use Committee in order to guarantee the utmost levels of ethics and respect for animal life in our R&D activities.

*Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects, a set of ethical guidelines for clinical research
Ethics in Clinical Research and Clinical Trials

Based on the Ethical Guidelines for Medical and Health Research Involving Human Subjects, Terumo has established the Terumo Ethical Review Regulations, a set of basic policies for respecting human rights and dignity in human clinical research (clinical trials). The Terumo Research Ethics Review Committee, which includes members from outside of the Group, has been formed in accordance with these regulations to discuss the social significance and scientific validity of all clinical research projects prior to commencement. The status of this committee’s activities is registered and disclosed through the Ethical Review Committee Reporting System of the Ministry of Health, Labour and Welfare.

Clinical trials aimed at the acquisition of manufacturing and sales approval are conducted in accordance with the principles of the Declaration of Helsinki and in compliance with GCP put forth in the relevant countries. GCP defines all of the items for which compliance is required by the medical institutions conducting clinical trials; healthcare professionals, such as research investigators, and other staff; and the sponsors of the study. The Terumo Group formulates and adheres to procedures based on GCP to ensure the quality of clinical trials and to acquire highly reliable data. Moreover, clinical trials are monitored to confirm adherence to the defined procedures and, most importantly, to ensure that the human rights and safety of trial participants are being prioritized.

Ethics in Animal Experiments

In its quest to fulfill the Group mission of “Contributing to Society through Healthcare,” Terumo performs research and development on medical devices, pharmaceuticals, regenerative medicine, and other products and provides training to healthcare professionals on the safe use of its products in medical settings. For these reasons, certain animal experiments are unavoidable. Those animal experiments that cannot be avoided are performed appropriately with due consideration to animal welfare.

Terumo has established internal regulations on animal experiments based on relevant laws and guidelines such as the Act on Welfare and Management of Animals and the Standards relating to the Care and Keeping and Reducing Pain of Laboratory Animals. We have also formed the Animal Care and Use Committee. The committee examines protocols, confirms the conclusion of experiments, performs animal husbandry management while taking animal welfare into consideration, and provides training for staff engaged in animal experiments to ensure that we adhere to the “Three Rs” stipulated by relevant laws—Replacement (to replace animal studies with other methods), Reduction (to use fewer animals), and Refinement (to alleviate pain and distress)—as well as to Terumo’s unique fourth R, Responsibility (to be responsible for experiments). Moreover, the Animal Care and Use Committee carries out self-inspections to assess compliance with the relevant laws, and third-party verification and certification is received from the Association for Assessment and Accreditation of Laboratory Animal Care International or the Japan Health Sciences Foundation. When contracting animal experiments to third-parties, Terumo verifies that subcontractors are practicing proper compliance.